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Title: Therapist differences in a randomised trial of the outcome of cognitive behaviour therapy for health anxiety in medical patients

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Abstract: Background:

Health anxiety is common in medical settings and can be treated successfully by cognitive behaviour therapy (CBT). However it is not clear who might be best placed to deliver this therapy.

Objectives:

In a planned secondary analysis of data from a randomised trial of adapted cognitive behaviour therapy for health anxiety we compared outcomes of therapy delivered by nurses and other professional groups.

Design:

A randomised controlled trial with two treatment arms, 5-10 sessions of cognitive behaviour therapy adapted health anxiety (CBT-HA) or standard care. The study is registered as ISRCTN14565822.

Setting: Cardiology, endocrine, gastroenterology, neurological and respiratory clinics in six general hospitals in the UK covering urban, suburban and rural areas.

Participants: Medical patients attending the clinics who had pathological health anxiety and also scored for a diagnosis of hypochondriasis.

Methods:

Patients were randomised to one of two treatment arms, 5-10 sessions of cognitive behaviour therapy adapted health anxiety (CBT-HA) or standard care delivered by naive therapists (not randomised) who were trained in advance before delivering the treatment. Independent assessment of outcomes by researchers masked to allocation status at 3m, 6m, 12m and 24m.

Results: 444 patients were randomised in the trial, 219 to CBT-HA and 225 to standard care. 373 (84%) completed assessments after two years. Those treated by nurses (n = 66) had improvement in health anxiety, generalised anxiety and depression outcomes that were significantly better and twice as great as those of the professional groups of assistant psychologists (n = 87) and graduate workers (n = 66)($p < 0.01$ over all time points). The number needed to treat (NNT) to show superiority of nurse-delivered treatment over other treatment delivery was 4 at 6 months and 6 at one year.

Conclusion: General nurses, after suitable training, are very effective therapists for patients with health anxiety in medical clinics and should be the therapists of choice for patients in these settings.

The study is registered as ISRCTN14565822.

Response to Reviewers: File attached with listed changes made in response to reviewer

14th November 2014

Dear Professor Norman,

Thank you for the comments of your third reviewer. We have made the necessary changes.

Best wishes,

Peter Tyrer

Therapist differences in a randomised trial of the outcome of cognitive behaviour therapy for health anxiety in medical patients

Helen Tyrer¹, Peter Tyrer¹, Yvonne Lisseman-Stones², Sharon McAllister³, Sylvia Cooper¹, Paul Salkovskis⁴, Michael J Crawford¹, Simon Dupont⁵, John Green⁶, David Murphy⁷, and Duolao Wang⁸

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'What is already known about the topic?'

- Nurses have often been employed as therapists for psychological treatments but are not generally regarded as competent as psychologists
- Health anxiety (formally called hypochondriasis) is very common in hospital clinics where psychologists are not often present to give therapy
- Cognitive therapy for health anxiety is effective when given by trained psychologists

'What this paper adds'

- In this large randomised trial in medical out-patient clinics two general nurses with no psychological experience, after preliminary training and supervision, were significantly superior to psychologists and other therapists in reducing health anxiety and related mood symptoms both after 3 and 6 months and after 2 years
- The findings suggest that nurses in medical clinics would be ideally suited to provide cognitive behaviour therapy for health anxiety in hospital settings

IJNS AUTHOR CHECKLIST *Authors of all papers should submit this checklist together with their manuscript. The checklist will be made available during the submission process online to all authors and full step-by-step guidance given.*

Part 1 identifies basic requirements for the manuscript submission (*mandatory for all submissions*)

Part 2 identifies recognized guidelines for scientific reporting, which you should use to prepare your manuscript (*required for systematic reviews and original research*)

Part 3 is a self assessment checklist that is designed to help to ensure that your research or review manuscript meets basic standards and the journal's Guide for Authors. (*optional only*)

PART 1 Basic requirements

Author response or further detail Tick

Word count: Total word count including references: 5282

Was ethical approval given and by whom? (give any reference number): North Nottingham Ethics Committee (08/H0403/56)

Please state any conflicts of interest: Stated in paper. PS developed CBT-HA and HT has published a book describing the treatment (Tyrer H (2013). Tackling Health Anxiety: a CBT Handbook., RCPsych Press)

Please state sources of funding and the role of funders in the conduct of the research: This research was funded by the National Coordinating Centre for Health Technology Assessment (NCCHTA) programme (project number 07/01/26). The views expressed in this publication are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS, or the Department of Health.

Please state any study registry number (e.g. ISRCTN): ISRCTN14565822

✓ Title The title is in the format 'Topic / question: design/type of paper' and identifies the population / care setting studied.

(e.g. *The effectiveness of telephone support for adolescents with insulin dependant diabetes: controlled before and after study: the structure is optional for discussion papers, editorials and commentaries*)

✓ Abstract A structured abstract appropriate to the design (see *guidelines for authors*). Reports of controlled trials should follow the CONSORT format (does not apply to editorials or commentaries, Abstracts for discussion papers need not be structured)

✓ Key words Between four and six key words have been provided in alphabetical order, which accurately identify the paper's subject, purpose, method and focus. Use the Medical Subject Headings (MeSH®) thesaurus or Cumulative Index to Nursing and Allied Health (CINAHL) headings where possible (see <http://www.nlm.nih.gov/mesh/meshhome.html>).

✓ What the paper adds Points have been included that identify existing research knowledge relating to the specific research question / topic (what is already known) and a summary of the new knowledge added by this study (see *Guide for Authors*, does not apply to editorials or commentaries)

✓ References Citations accord to the journal's format (Author, date) and reference list includes full details of all cited references in the proper format and alphabetical order (see *Guide for Authors*)

Other Published accounts

✓ All published and in press accounts of the study from which data in this paper originate are referred to in the paper and the relationship between this and other publications from the same study is made clear (see *Guide for Authors*)

The study is referred to by a distinctive name which will be used in any future publications to identify that it as the same study.

✓ Please upload copies of all previous, current and under review publications from this study and / or give full details below

Seivewright H, Green J, Salkovskis P, Barrett B, Nur U, & Tyrer P (2008). Randomised controlled trial of cognitive behaviour therapy in the treatment of health anxiety in a genitourinary medicine clinic. *British Journal of Psychiatry*, 192, 332-337.

Tyrer P, Cooper S, Tyrer H, Salkovskis P, Crawford M, Green J, Smith G, Reid S, Dupont S, Murphy D, Byford S, Wang D & Barrett B. (2011). CHAMP: Cognitive behaviour therapy for health anxiety in medical patients, a randomised controlled trial *BMC Psychiatry*, 11, 99

Tyrer P, Cooper S, Crawford M, Dupont S, Green J, Murphy D, Salkovskis P, Smith G, Wang D, Bhogal S, Keeling M, Loeberberg G, Seivewright R, Walker G, Cooper F, Evered R, Kings S, Kramo K, McNulty A, Nagar J, Reid S, Sanatinia R, Sinclair J, Trevor D, Watson C, Tyrer, H (2011). Prevalence of health anxiety problems in medical clinics. *Journal of Psychosomatic Research*, 71, 392-394.

Barrett B, Tyrer P, Tyrer H, Cooper S, Crawford MJ & Byford S. (2012). An examination of the factors that influence costs in medical patients with health anxiety. *Journal of Psychosomatic Research*, 73, 59-62.

Tyrer P, Cooper S, Salkovskis P, Tyrer H, Crawford M, Byford S, Dupont S, Finnis S, Green J, McLaren E, Murphy D, Reid S, Smith G, Wang D, Warwick H, Petkova H, & Barrett B. (2014). Clinical and cost-effectiveness of cognitive behaviour therapy for health anxiety in medical patients: a multicentre randomised controlled trial.. *Lancet*, 383, 219-225.

PART 2

Standards of reporting

The editors require that manuscripts adhere to recognized reporting guidelines relevant to the research design used. These identify matters that should be addressed in your paper. Please indicate which guidelines you have referred to.

These are not quality assessment frameworks and your study need not meet all the criteria implied in the reporting guideline to be worthy of publication in the IJNS. The checklists do identify essential matters that should be considered and reported upon. For example, a controlled trial may or may not be blinded but it is important that the paper identifies whether or not participants, clinicians and outcome assessors were aware of treatment assignments.

****You are encouraged (although not required) to submit a checklist from the appropriate reporting guideline together with your paper as a guide to the editors and reviewers of your paper.**

Reporting guidelines endorsed by the IJNS are listed below:

Guideline referred to Checklist submitted**

Observational cohort,
case control and
cross sectional
studies

STROBE **S**trengthening the **R**eporting of **O**bservational Studies in **E**pidemiology
<http://www.equator-network.org/index.aspx?o=1032>

Quasi experimental /
non-randomized
evaluations

TREND - **T**ransparent **R**eporting of **E**valuations with **N**on-randomized **D**esigns
<http://www.equator-network.org/index.aspx?o=1032>

Randomised (and
quasi-randomised)
controlled trial

✓ **CONSORT** – **C**onsolidated **S**tandards of **R**eporting **T**rials
<http://www.equator-network.org/index.aspx?o=1032>

Study of Diagnostic
accuracy /
assessment scale

STARD **S**tandards for the **R**eporting of **D**iagnostic **A**ccuracy studies
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**Systematic Review of
Controlled Trials**

PRISMA - **P**referred **R**eporting **I**tems for **S**ystematic **R**eviews and **M**eta-**A**nalyses
<http://www.equator-network.org/index.aspx?o=1032>

**Systematic Review of
Observational
Studies**

MOOSE **M**eta-analysis of **O**bservational **S**tudies in **E**pidemiology
<http://www.equator-network.org/index.aspx?o=1032>

Qualitative researchers might wish to consult the guideline listed below

Qualitative studies COREQ: Consolidated criteria for reporting qualitative research Tong, A., Sainsbury, P., Craig, J., 2007. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care* 19 (6), 349-357. (<http://dx.doi.org/10.1093/intqhc/mzm042>)

Other (please give source)

Not applicable



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	3-4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	
Statistical methods	11b	If relevant, description of the similarity of interventions	4
	12a	Statistical methods used to compare groups for primary and secondary outcomes	6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	15
	13b	For each group, losses and exclusions after randomisation, together with reasons	15
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	16-19
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	16-19
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	16-19
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	12
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	11

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Therapist differences in a randomised trial of the outcome of cognitive behaviour therapy for health anxiety in medical patients

Abstract

Background:

Health anxiety is common in medical settings and can be treated successfully by cognitive behaviour therapy (CBT). However it is not clear who might be best placed to deliver this therapy.

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Independent assessment of outcomes by researchers masked to allocation status at 3m, 6m, 12m and 24m.

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Conclusion: General nurses, after suitable training, are very effective therapists for patients with health anxiety in medical clinics and should be the therapists of choice for patients in these settings.

The study is registered as ISRCTN14565822.

Introduction

Health anxiety is a relatively new diagnosis in psychiatry that has partly replaced the previous one of hypochondriasis, now abandoned in the latest US classification, DSM-5¹⁻². Because of this change there are limited data on its prevalence but it does appear to be a common condition in the community (3.5%)³ and in secondary medical care (20%)⁴. These figures for health anxiety are much greater than those for hypochondriasis, which is a confusing diagnosis of limited acceptability⁵⁻⁶. Health anxiety leads to unnecessary use of health services⁷ because of additional medical consultations and investigations. Following a pilot study showing the effectiveness of cognitive behaviour therapy (CBT) delivered by expert therapists⁸ we set up the CHAMP (Cognitive behaviour therapy for Health Anxiety in

1 Medical Patients) trial to examine the effectiveness and cost-effectiveness of a modified
2 cognitive behavioural treatment for health anxiety (CBT-HA) with assessment of outcomes
3 over a two-year period. At the time the study was formulated we planned to have all
4 therapy delivered by nurses working in or close to the clinics concerned, in order to test a
5 model that could be used to deliver therapy more widely if it were found to be successful.
6 Unfortunately this was not possible (for mainly financial reasons) and so other therapists
7 generally naive to the specific form of cognitive therapy to be given, including assistant
8 psychologists and other graduate professionals were also included in the staff to deliver the
9 therapy in our final protocol⁹.

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19 This paper is not concerned with the overall effectiveness of the treatment, as this has been
20 demonstrated previously; there was greater benefit in the symptomatic improvement of
21 health anxiety and generalised anxiety over the two year period¹⁰. This paper examines the
22 outcome separated by therapist type, with a particular emphasis on the effectiveness of the
23 therapy given by nurses and possible reasons given for this.

24 25 26 27 28 29 30 31 **Methods**

32 The CHAMP trial involved two parallel arms with randomization of eligible patients to 5-10
33 sessions of CBT-HA or to standard care in the clinics. Assessments of health anxiety,
34 generalised anxiety, depression, social function, quality of life and costs were made over a
35 two year period after randomization. The primary outcome was change in the score of
36 health anxiety using a standard instrument¹¹. Secondary hypotheses were that health
37 anxiety at other time points, generalised anxiety and depression, social functioning and
38 quality of life measured by standard measures¹²⁻¹⁴ would differ between CBT-HA and
39 standard care and that CBT-HA would be a cost-effective use of resources.

40 41 42 43 44 45 46 47 48 49 50 51 **Participants**

52 All patients over a 20 month period attending medical out-patient clinics in cardiology,
53 endocrinology, gastroenterology, neurology and respiratory medicine in 6 general hospitals,
54 King's Mill Hospital (North Nottinghamshire), St Mary's Hospital (London), Charing Cross
55 Hospital (London), Hammersmith Hospital (London), Chelsea and Westminster Hospital
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(London), and Hillingdon Hospital (Middlesex), were approached by research assistants by agreement with the staff concerned and offered the opportunity to complete a form described as 'a scale to see how much you worry about your health'. This scale, the Health Anxiety Inventory, was given to 28,990 people but only those who scored 20 or more on the scale were further involved.

Randomisation and masking

Eligible patients in whom consent was provided were allocated in a 1:1 ratio to the two arms of the study according to a computer-generated random sequence using block randomisation with varying blocksize of four and six. The allocation sequence was not available to any member of the research team until databases had been completed and locked. There was no randomisation of therapists as the provision of therapy was determined by the personnel available at each treatment site.

Treatments

CBT-HA arm

Cognitive therapy adapted for health anxiety (CBT-HA) was given to patients allocated to the active treatment group. This was based on the model first described by Salkovskis and Warwick¹⁵ and, although based on standard cognitive therapy principles, differed in focusing especially on the need for reassurance, hypervigilance, and fear of (rather than actual) disease that are core to the condition. The plan outlined at the beginning was to offer between 5 and 10 sessions of one hour each but this was allowed to be flexible and booster sessions were also permitted after the end of therapy if required. The intention was to start treatment within two weeks of allocation and complete most therapy within 3-6 months.

Standard care

Patients allocated to standard care had information given about health anxiety in the course of baseline assessment but subsequently had no further psychological input. They continued to attend relevant practitioners in primary and secondary care as considered necessary.

Therapists

To reinforce the pragmatic nature of the trial we did not use experts in cognitive behaviour therapy to give the treatment as these are seldom available in medical settings except for specialised cases. Instead, naive therapists with an interest in administering the modified treatment were trained in two workshops carried out by four supervisors headed by PS and HT, and in addition each therapist received supervision from a more senior practitioner at 2-4 week intervals during therapy. Patients allocated to the CBT arm of the trial were allocated to the next available therapist. The type of therapist was not randomised and all were recruited from staff available at each site. Of a total of 17 therapists, 10 were psychologists in training, 5 were graduate workers (including one dietician), and two were nurses.

Training and Fidelity of Intervention

Four experts in the treatment trained the therapists at two workshops and also assessed treatment fidelity, together with HW. 50% of all treatment sessions were audio recorded. Fidelity was tested using the health anxiety modification of the Cognitive Therapy Rating Scale (CTRS-HAV)¹⁶. Recordings were assessed by the local supervisor and a random sample sent to a supervisor at a different site to assess the level of agreement, with further training ending only when an agreement level of 0.80 kappa was reached.

The study was approved by the North Nottingham Ethics Committee (08/H0403/56) prior to the start of data collection.

Inclusion and exclusion criteria

Those who satisfied the criteria for excessive health anxiety above were included if they were (i) aged between 16 and 75, (ii) resident in the area, (iii) had sufficient understanding of English to read and complete study questionnaires, and (iv) gave written consent for the interviews, audio-taping of 50% of treatment sessions, and (v) gave permission to access their medical records. The presence of existing medical pathology, provided it was not a

new diagnosis requiring further investigation, was not a study exclusion criterion. Those that were felt clinically to have a level of continuing major pathology that was too severe for them to take part in the study, including progressive cognitive impairment, terminal disorders, and any major comorbid pathology that would interfere with psychological treatment, those who were currently being actively investigated for significant pathology suspected by the clinician and for whom cognitive behaviour therapy might confuse or cause distress, and any currently under psychiatric care were also excluded.

Assessments of health anxiety (HAI),¹¹ anxiety and depression (HADS)¹², social functioning (SFQ)¹³ and health-related quality of life (EQ-5D),¹⁴ were made at baseline and assessed independently by research assistants at 6m, 12m and 2 years. The quality of life measure was linked to the economic assessment and neither are being considered here. Health anxiety scores (HAI) were additionally recorded at 3 months.

Statistical analysis

The calculation of the sample size for the main study has been described previously⁹, and was powered to assess the superiority of CBT-HA over standard care. The current study was an exploratory comparison of the outcomes of the different therapists and no formal sample size calculation was performed.

All analyses were based on the intention-to-treat principle. The primary endpoint was analysed using a mixed model with time, treatment group (nurses, graduate workers, assistant psychologists, and standard care), and time x treatment interaction as fixed effects, baseline measurement as covariate, and patient as random effect. The treatment differences between group comparisons, including one between nurses, graduate workers and assistant psychologists combined, were calculated at each time point (3m, 6m, 1 year and 2 years). These differences, together with their 95% confidence intervals (CI), were derived from the mixed model. Other secondary endpoints were analysed in the same way.

Other assessments were analysed in a similar way. In addition, the percentage of patients achieving normal levels of health anxiety ($HAI \leq 10$) or significant improvement ($HAI \leq 15$) were compared using a generalised estimating equation model with visit, treatment, interaction between visits and treatment as fixed effect, baseline measurement of HAI as covariate, and patient as random effect (an exchangeable covariance structure).

Results

[Figure 1 near here]

445 patients were randomised to the trial and 376 (76%) completed the follow-up after two years (Figure 1). One patient was randomised twice in error, both times to standard care; only the first of the assessments was used. Proportions followed up at other time points are shown elsewhere¹⁰. The 219 patients randomised to CBT-HA were seen by a total of 17 therapists. In patients allocated to CBT-HA there was a significantly greater reduction in both health anxiety and generalised anxiety symptoms than in the standard care group at all times of testing¹⁰. The present paper focuses on the differences between therapists in accounting for these differences.

[Tables 1 and 2 near here]

Of the 219 patients referred to CBT-HA, 66 (30%) were referred to nurses ($n=2$) for their treatment, 66 (30%) to graduate workers ($n=5$) and 87 (40%) to assistant psychologists ($n=10$). Details of the demographic characteristics of the 17 therapists are shown in Table 1. The two nurses differed from the other therapists in having less general knowledge of CBT, being paid higher salaries, and seeing more patients than other therapists. The three groups were chosen as they shared some common characteristics; nurses (both trained in general nursing), assistant psychologists (a relatively homogeneous group of psychologists who had some knowledge of CBT in theory and practice), and a more heterogeneous group of graduate workers, including a dietician, graduates in psychology or a related discipline who may have had teaching in CBT but very little in the way of practice, and a physician (HT) who

1 had much more experience and acted as a back-up in the study in all centres when no other
2 therapists were available. Because of the limited availability of funding there were
3 important differences in the distribution of therapists by site. Because funding and
4 personnel were available for nurses to be employed at one site (Kings Mill Hospital,
5 Nottinghamshire) almost all the patients treated there were seen by two nurses (SM and YL-
6 S). The distribution by site of the three groups also showed great variation (Table 2).
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11 ***Outcome by therapist group***

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16 15 patients did not respond to the invitation for treatment after randomisation and 6 more
17 did not attend initially but did have some form of contact later. Of the numbers who did not
18 attend any sessions there were fewest in the nurse group than in the other two (Table 2)
19 but this was not significant ($\chi^2 = 3.18$, df 1, $P=0.07$). The mean number of CBT-HA treatment
20 sessions was 6 (range 0-22). The overall differences between CBT-HA and standard care
21 were highly significant at all assessment points, including 12 months, the primary outcome
22 point (difference=2.98, 95% CI, 1.64 to 4.33, $p<0.001$). These differences were maintained
23 in further analyses with site and baseline scores as covariates.
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35 [Figure 2 and Tables 3-6 near here]
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40 The primary outcome in the main trial was the change in HAI scores after 1 year. This
41 showed a highly significant benefit for CBT-HA in the main trial¹⁰ but when the results were
42 separated by therapist type it was clear that the largest component of this difference came
43 from the nurse-treated therapists, where significant superiority was found over the other
44 groups and standard care at all time of testing. The differences at all time points are shown
45 in Figure 2 and the statistical findings in Tables 3 and 4. This superiority was also shown to
46 a lesser, but still significant degree for generalised anxiety (HADS-anxiety score)(overall
47 $p=0.002$), depression (HADS-depression score)($P=0.02$), and social functioning (SFQ)($p = 0.03$
48 at 6m and $p = 0.06$ overall)(Table 3). The number needed to treat (NNT) to show superiority
49 of nurses over the other two therapy groups combined was 4 at 3m and 6m and 6 at one
50 year.
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1 The mean number of treatment sessions for each of the groups was 7.7 in the nurse group,
2 5.7 in the assistant psychologist one, and 4.7 in the graduate worker group, and linear
3 regression of session numbers showed significantly greater number of sessions in the nurse
4 treated group ($P<0.001$)(Table 5). The proportion of patients in the nurse-treated group who
5 improved (a score of 15 or less on the HAI) at one year (the primary outcome point) was
6 53.2% compared with the graduate worker group (42.1%), assistant psychologists (25.3%)
7 and standard care (21.8%)($p<0.01$) and over all time points this superiority was even more
8 marked ($P<0.0001$)(Table 6). Similar findings were shown in the proportions of those who
9 recovered (ie, had an HAI score of 10 or less at one year) ranging from 24.2% in nurse-
10 treated patients to 4% in those treated by assistant psychologists ($p<0.01$).
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20 **Fidelity of therapists**

21 Assessments of the fidelity of therapists' treatment showed that all except one, an assistant
22 psychologist, scored at an adequate competence level or higher, and this was confirmed by
23 an independent assessor. The two nurses scored slightly above the 50th percentile of all
24 therapists on the scale (details given in this format as the scale has not yet been validated)
25 but five therapists scored higher, two of these were in the graduate group and three in the
26 assistant psychologist one.
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35 **Cost-effectiveness of nurses**

36 The study had a cost-effectiveness component built into the protocol⁹ and the results
37 overall showed the study was cost-neutral, but the total costs were dwarfed by the very
38 large costs of those who had severe medical illnesses associated with their health anxiety
39 (Nikita da Cunha, 2014, BSc thesis, Imperial College) and so savings elsewhere were small in
40 comparison¹⁰. Excess treatment costs are not covered by grants in research supported by
41 major research bodies in the UK and have to be provided by NHS Trusts or other bodies. We
42 were fortunate in getting some funding from a subvention fund at the Department of Health
43 to pay for the nurses and two therapists elsewhere and the other costs were met by NHS
44 Trusts in London. But this funding was very difficult to obtain and most had to be provided
45 at the lowest rate possible. It was therefore impossible to meet the original requirement for
46 all, or even the majority, of therapists to be nurses working in the general hospitals.
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Discussion

The results of this trial should be seen in the general context of the employment of nurses in the delivery of psychological treatments. It has been well demonstrated that naïve nurses, including both those who are generally and mental health trained, are competent at delivering behavioural and cognitive behaviour therapies in a range of medical settings, mostly for depressive symptoms¹⁷⁻²² but this study is the first to suggest superiority of nurses over other professional disciplines, including psychologists. The main limitation of the study is that the patients were not randomised to the therapists and so there could be confounding factors.

The patients seen by the nurses had more treatment sessions and lower drop-out rates, and saw more patients than any of the other therapists. They also saw patients at only one site in the trial and had the same supervisor (HT) throughout. These may have accounted for a small part of the difference in efficacy, as better outcomes follow increased experience²³, but there is no reason to believe that patients with health anxiety are fundamentally different in North Nottinghamshire than elsewhere in the country. The possibility that nurses were better accepted by patients and were seen as more informed was not tested in the study but has resonance in explaining the differences. Both the nurses involved in the study were experienced mature general nurses, whereas most of the other therapists were considerably younger and less experienced. The obvious inference is that the nurses were naturally more knowledgeable about medical disorders than other therapists in other groups. It would therefore not be surprising that patients might have more confidence in being treated by a nurse, rather than a psychologist or other professionals independent of normal medical care. The lower drop-out rates in the nurse-treated group also supports the hypothesis that they were accepted more readily as therapists.

1 The findings of this trial suggest nurses would be more appropriate than assistant
2 psychologists in delivering CBT-HA in medical settings. This conclusion has to be qualified in
3 view of the comments above and needs to be replicated, not least as there are now many
4 studies showing that psychologists, usually with significantly more training than the ones in
5 our study, are very effective as therapists for pathological health anxiety²⁴⁻²⁷ and also in
6 development of the treatment by the Internet²⁸⁻²⁹, where superiority of CBT-HA has been
7 shown over stress management approaches²⁹. The importance of the findings lies in the
8 development of this treatment. If staff are to be trained to deliver CBT-HA in medical clinics
9 nurses would seem to be a more appropriate choice than the current practice of referring
10 patients to psychologists. This would also confer advantages in helping to destigmatise
11 health anxiety by regarding it as a medical rather than psychiatric concomitant of health
12 concerns. This form of management could be incorporated into medical clinics and be
13 administered by trained staff such as cardiac rehabilitation nurses and other specialist staff
14 in other medical clinics who treat repeated attenders, many of whom have existing medical
15 pathology but who suffer unduly from persistent and unnecessary worry over their health.
16 This change would add to the increasing interest in showing that nurses can take on some of
17 the duties of medical staff effectively³⁰.

33 Conflicts of interest:

34 PC developed CBT-HA, and HT is the author of a book describing CBT-HA in practice.

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ENROLLMENT

Assessed for eligibility (n = 5769)

Excluded (n = 5324)

- Not meeting inclusion criteria (n = 1389)
- Declined to participate (n = 3935)

Randomized (n = 445)(1 twice)

CBT-HA

Standard care

ALLOCATED

Allocated for intervention (n = 219)

- Received allocated intervention (n = 204)
 - Did not receive allocated intervention (n = 15)
- Reason(s) :
Did not attend for treatment sessions (n = 15)

Allocated for intervention (n = 225)

- Received allocated intervention (n = 225)
- Did not receive allocated intervention (n = 0)

FOLLOW UP

Lost to follow up (n = 29)

Reason(s) :
withdrew from assessment (n = 4)
unable to collect data (n = 22)
died (n = 3)

Discontinued intervention (n = 0)

Lost to follow up (n = 42)

Reason(s) :
unable to collect data (n = 30)
withdrew from follow-up (n = 6)
died (n = 6)

Discontinued intervention (n = 0)

ANALYSIS

Analysed (n = 219)

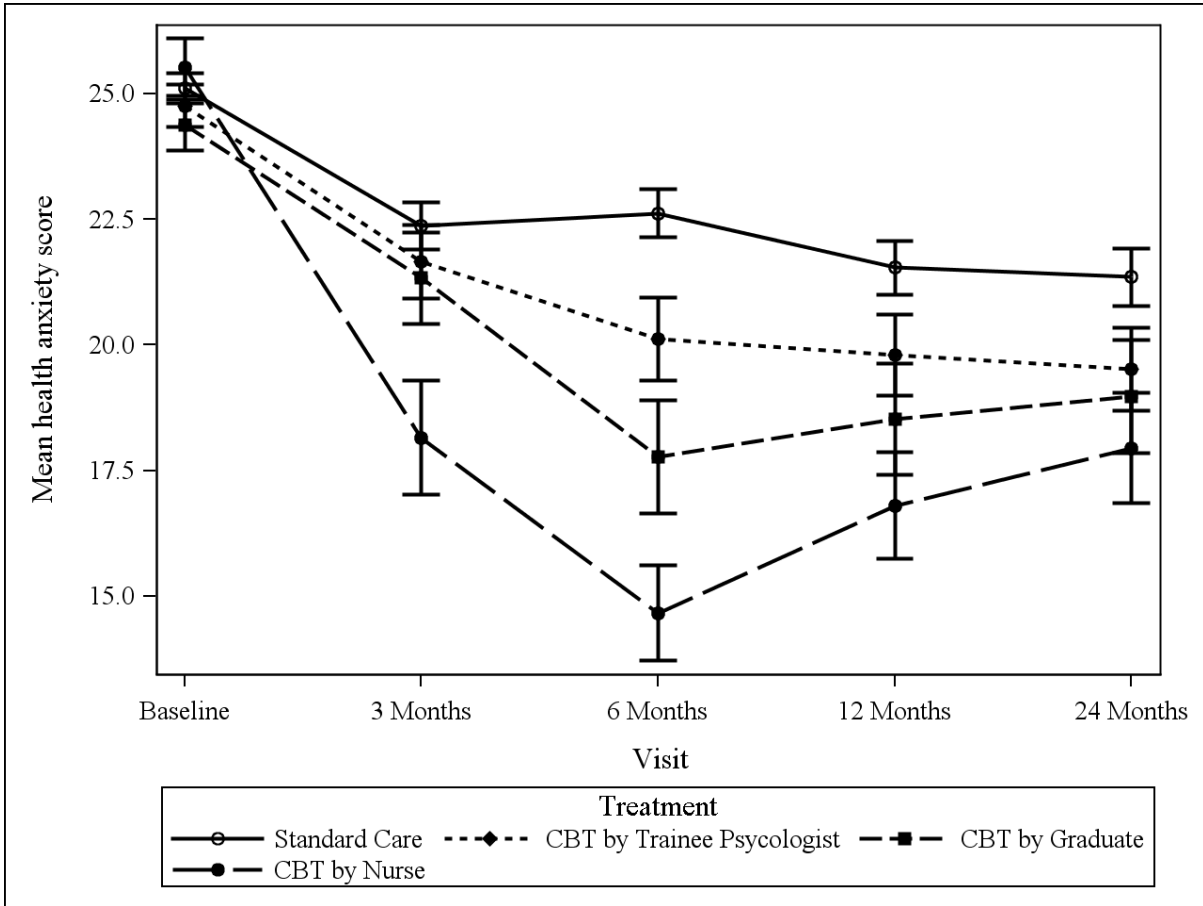
Excluded from analysis (n = 0)

Analysed (n = 225)

Excluded from analysis (n = 0)

Figure 1 - Consort diagram – attached separately as not sure if needed

Figure 2: Mean differences from baseline in Health Anxiety Inventory (HAI) scores between the outcomes of 219 patients with health anxiety treated by nurses (n=66), graduate workers (n=66) and assistant psychologists (n=87) at four time points in the CHAMP trial



See Table 3 for details of statistical differences

Table 1. Differences in experience and knowledge of CBT by therapist type

Group for analysis of data	Years of professional experience	Previous training in CBT	Previous experience in delivering CBT	Total patients referred	Total patients not seen (%)
Nurses (n=2)(Band 6)	>25	0%	0%	66	3 (4.5)
Graduates (n = 5)	5-26	40%	20%	66	10 (15)
Assistant psychologists (n=10)	<10	100%	50%	87	8 (10.3)

Table 2. Distribution of therapist discipline in the cognitive therapy (CBT-HA) group by hospital site

Site	Nurses	Graduates	Assistant psychologists	Total referred	Total seen
Kings Mill Hospital, Nottinghamshire	66	4	0	70	66
Charing Cross Hospital and Hammersmith Hospitals, London	0	27	4	31	28
St Mary's Hospital, London	0	6	30	36	28
Chelsea & Westminster Hospital, London	0	25	1	26	23
Hillingdon Hospital, Middlesex	0	4	52	56	53
Totals	66	66	87	219	198

Table 3 : Comparison of health anxiety outcome using the Health Anxiety Inventory (HAI) separated by therapist group in 444 randomised patients

		N, mean(SD)					Difference between nurses and other groups Mean (95% CI), p-value
	Visit	Standard care	CBT by Assistant psycholog ists	CBT by Graduates	CBT by Nurses	All	
Mean scores on Health Anxiety Inventory (HAI)	Baseline	225, 25.12(4.52)	87, 24.76(3.91)	66 24.38(4.15)	66, 25.53(4.67)	225 25.12(4.52)	
	3 Months	212 22.37(6.71)	82 21.65(6.62)	59 21.33(6.97)	64 18.15(9.07)	212 22.37(6.71)	4.10 (6.1-3.1) P<0.0001
	6 Months	204 22.62(6.81)	78 20.13(7.26)	56 17.77(8.42)	63 14.67(7.53)	204 22.62(6.81)	4.93 (7.0-2.9) P<0.0001
	12 Months	193 21.54(7.45)	75 19.80(6.96)	57 18.53(8.31)	62 16.81(8.31)	193 21.54(7.45)	3.24 (5.3-1.2) P<0.002
	24 Months	183 21.35(7.67)	76 19.51(7.22)	53 18.98(8.14)	61 17.95(8.63)	183 21.35(7.67)	2.49 (4.5-0.5) P<0.02
	All periods						3.7 (5.4-2.0) P<0.0001

Table 4 : Comparison of generalised anxiety and depression (HADS), and social functioning outcomes (SFQ) separated by therapist group in 444 randomised patients

Measure	Visit	N Mean(SD)					Difference between nurses and other groups Mean (95% CI), p- value
		Standard care	CBT by Assistant psychologist s	CBT by Graduates	CBT by Nurses	All	
Hospital Anxiety and Depression Scale -HADS Anxiety	Baseline	225 12.25(3.88)	87 12.45(3.77)	66 12.62(3.57)	66 12.65(3.91)	444 12.41(3.81)	
	6 months	204 10.96(4.16)	78 10.63(4.37)	56 9.96(4.99)	63 8.51(4.61)	401 10.37(4.47)	1.90 (3.1-0.7) P<0.002
	12 months	192 10.57(4.33)	75 10.37(4.04)	57 9.84(5.01)	62,9 06(4.38)	386 10.18(4.41)	1.28 (2.5-0.1) P=0.035
	24 months	181 10.13(4.74)	75 9.27(4.13)	53 10.00(4.17)	61,8 54(4.70)	370 9.67(4.56)	1.51 (2.7-0.3) P=0.013
	All periods						1.6 (2.5-0.6) P=0.002
Hospital Anxiety and Depression Scale – HADS Depression	Baseline	225 8.83(4.58)	87,8 53(3.83)	66 8.65(3.99)	66 10.36(5.06)	444 8.97(4.46)	
	6 months	204 8.43(4.71)	78 8.38(5.14)	56 7.50(4.57)	63 7.57(4.39)	401 8.16(4.73)	1.47 (2.7-0.3) P=0.02
	12 months	192 8.41(4.90)	75 8.27(5.32)	57 7.35(4.85)	62 8.10(5.02)	386 8.18(4.99)	0.77 (2.0-(- 0.5)) ns
	24 months	181 8.34(5.31)	75 8.00(5.44)	53 7.77(4.99)	61 7.74(5.04)	370 8.09(5.23)	1.43 (2.7-0.2) P=0.02
	All periods						1.22 (2.3-0.2) P=0.02
Social Functioning Questionnair e (SFQ)	Baseline	225 9.49(4.32)	87,9.09(4.82)	66,9.51(4.45)	66,9.77(4.92)	444,9.45(4.52)	
	6 months	204 9.28(4.86)	78,10.02(5.3 0)	56,8.40(5.59)	63,8.35(4.89)	401,9.15(5.07)	1.32 (2.5-0.13) P=0.03
	12 months	192 9.11(5.06)	75,9.07(4.94)	57,8.97(5.94)	62,8.60(4.91)	386,9.00(5.14)	0.81 (2.0-(-0.39)) ns
	24 months	182 8.69(5.07)	76,8.51(5.24)	53,8.09(5.33)	61,8.27(4.70)	372,8.50(5.07)	0.76 (2.0-(-0.44)) ns
	All periods						0.96 (2.0-(-0.04)) P=0.06

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Table 5: Summary results from linear regression analysis of number of sessions separated by therapist group

Comparison	Difference	95% CI		Probability
		Lower Limit	Upper Limit	
Graduates vs Assistant psychologists	-0.97	-2.26	0.32	0.1396
Nurses vs Assistant psychologists	2.03	0.74	3.32	0.0022
Nurses vs Graduates	3.00	1.63	4.37	<.0001
Nurses vs other groups combined	2.52	1.35	3.68	<.0001

Table 6. Proportions of patients showing significant improvement (HAI≤15) after one year

Therapist Group	Phase in trial	Number of patients (%) with HAI scores ≤15	Odds ratio of improvement compared with standard care -all times (sig)	95% Confidence Interval
Standard care	3 months	31 (14.6)		
	6 months	30 (14.7)		
	12 months	42 (21.8)		
	24 months	43 (23.5)		
CBT-HA – Assistant psychologists	3 months	16 (19.5)	1.58 (P =0.05)	0.99-2.51
	6 months	24 (30.8)		
	12 months	19 (25.3)		
	24 months	22 (28.9)		
CBT-HA - Graduates	3 months	10(16.9)	2.05 (P =0.005)	1.25-3.36
	6 months	24(42.9)		
	12 months	24(42.1)		
	24 months	18(34.0)		
CBT-HA - Nurses	3 months	28(43.8)	3.16 (P<0.0001)	1.97-5.06
	6 months	40(63.5)		
	12 months	33(53.2)		
	24 months	27(44.3)		

RESPONSE TO REVIEWER 3

Reviewer #3: The changes the authors have made to this paper have much improved it and I would support it's publication. The only comment I have is that there is still a suggestion that the comparison was with trained "qualified" psychologists in places and this needs to be changed.

The changes required are:

1. What this paper adds - first bullet point - should say perhaps '...significantly superior to other naïve therapists including assistant psychologists'

Response: Change made to 'What this paper adds' to include this

2. Discussion, first paragraph ...'...the first to suggest superiority of nurses over assistant psychologists"

Response: Done

3. Discussion, second paragraph, penultimate sentence: '...rather than an assistant psychologist or other naïve therapist' (it said 'other health professional but some weren't - a psychology graduate is not a health professional)

Response: There is no agreement on this – many assistant psychologists would regard themselves as integral health professional but we have removed the adjective 'health'. 4.

4. Discussion, third paragraph first sentence'... more appropriate than assistant psychologists ...'

Response: Done

5. Discussion, third paragraph second sentence '... there are now many studies showing that trained? psychologists ...' - are these studies you cite with assistant psychologists or qualified ones? perhaps specify?

Most of these have used trained psychologists (from our knowledge of the people involved) but in many of them there is no mention of training, but 'most' has been added as a reasonable qualifying adverb.

What this paper adds

We already know that nurses are competent at delivering many forms of psychological therapy once they have been sufficiently trained. This paper shows that for a specific form of therapy, cognitive behaviour therapy adapted for health anxiety given to medical patients, the performance of general nurses trained specifically in this treatment, is significantly superior to other naïve therapists including assistant psychologists in both the short term and over a two year period. Nurses should be the therapists of choice in this setting.